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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/349,713	07/08/1999	HERWIG BUCHHOLZ	MERCK-1900	7039

23599 7590 08/13/2002

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EXAMINER

SHARAREH, SHAHNAM J

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 08/13/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Offic Action Summary</b>	Application No.	Applicant(s)
	09/349,713	BUCHHOLZ ET AL.
Examiner	Art Unit	
Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 4/16/2002, 5/22/2002.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10, 12-14, 26 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10, 12-14 and 26 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

***Continued Prosecution Application***

The request filed on May 22, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/349,713 is acceptable and a CPA has been established. An action on the CPA follows.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 12-14, 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation of "synergistically effective amounts of isoquercitrin" which renders the claim ambiguous as it is not clear for what purpose or in what amount is isoquercitrin used for to provide a synergistically effective amount.

The phrase "where the composition is substantially purified of flavones or flavonoids other than isoquercitrin or the other component" is ambiguous. First, the recitation of "substantially purified" appears relative because it is not clear to what is the bases of comparison for the degree of purification. In essence, any detectable flavone or flavonoid is a purified flavone. Thus, the recitation appears vague.

Second, it is not clear what is meant by the entire phrase? In the amendment filed on April 19, 2002, Applicant asserts that the phrase merely indicates that a purified isoquercitrin is used. However, the recitation of claim is directed to ".compositions purified of flavones or flavonoids other than isoquercitrin or the other components." It is

clear from the scope of the pending claims that other flavonoids can be incorporated into the claimed composition, thus, the recitation appears to be in contradiction to the entire scope of claim.

***Claim Objection***

Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 12. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Toyo Seito et al JP 07-002677 (“JP ‘677”).

The instant claims are directed to compositions comprising isoquercitrin, a vitamin, and another component selected from the group 5-ethyldeoxyuridine, quercetin, galangin, kaempferol, propolis, chrysin, apigenin, luteolin, acecetin, eriodictyol, quercitrin, catechol, hesperitin, rutin and a glycoside thereof.

JP ‘677 discloses oral compositions comprising alpha-glucosylated rutin and at least one kind of compound selected from rutin, quercetin, isoquercitrin, hesperidins,

naringin and methylhesperidin (see abstract). Compositions of JP '677 also contain a vitamin such as vitamin C (see para. 0013 and 0039). Thus, JP '677 anticipates the limitations of the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-10 12-14, 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seito et al JP '677 in view of Lanzendorfer et al WO 96/18381 ("Lanzendorfer"), Fujirebio et al JP 04234320 ("JP '320") and Bean US Patent 4,132,782 ("Bean").

The teachings of JP '677 are described above. Primarily JP '677 is used to show oral compositions containing combination of two flavones, wherein one is isoquercitrin (see abstract, para 0013, 0039, claims 1-2). JP '677 does not teach doses of isoquercitrin as an antiviral agent nor does it explicitly teach topical formulation of isoquercitrin.

Lanzendorfer discloses topical and oral flavonoid containing compositions comprising various vitamins, UVB or UVA filters and at least one flavone including quercetin and isoquercetin derivatives. Given the fact that isoquercetin is one of the four subspecies of quercetin, the teachings of Lanzendorfer also encompass utility of isoquercetin. Lanzendorfer also indicates antiviral activity with his composition (see abstract, page 3-5, 43, 54-60, claims 1-7, and examples, example 27 is an oral preparation). Lanzendorfer does not specifically teach antiviral formulations.

JP '320 and Bean are collectively used to show the antiviral activity of isoquercitrin and suitable doses thereof. JP '320 teaches effective doses of isoquercitrin for treatment Hepatitis B Virus (HBV) (see abstract). Bean is also used to show the effectiveness of topical isoquercitrin against herpes simplex virus and useful doses thereof. (see abstract, col 2, lines 15-20). JP '320 and Bean do explicitly teach isoquercitrin compositions with a vitamin or a UV filter.

The teachings of JP '677, JP 320, Bean and Lanzendorfer are analogous because they all teach various compositions and utilities of flavones containing compositions.

Although Seito does not teach topical compositions of isoquercitrin containing a UV filter, it would have been obvious to one of ordinary skill in the art at the time of invention to use the teachings of Lanzendorfer and modify the isoquercitrin formulations of Seito for the purposes of preparing a topical composition of isoquercitrin with a UV filter, because as taught by Lanzendorfer preparing such topical formulations of flavones is conventional, and one of ordinary skill in the art would have been motivated to formulate topical formulations to reduce systemic side effects.

Further, it would have been obvious to one of ordinary skill in the art at the time of invention to use such compositions for their anti-viral activity, since as taught by JP '320 and Bean, it was well known in the art that isoquercitrin has antiviral activity against various species of viruses including herpes simplex virus.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on 703-308-4612. The fax phone numbers

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for the organization where this application or proceeding is assigned are 703-308-4556  
for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or  
proceeding should be directed to the receptionist whose telephone number is 703-308-  
1123.

ss  
August 9, 2002

*RJ*  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200